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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/129,298	08/05/1998	CHARLES J. ARNTZEN	7991-023-999	4312

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/129,298

Applicant(s)

ARNTZEN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 7 June 2002, as Paper No. 20.
2. The rejection of claims 2, 8, 17, 19 and 20 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn in view of Applicant's amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

DETAILED ACTION

4. Claims 1-4 and 8-27 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making a localized mutation in a target plant ALS gene or a transgenic GFP gene *in situ* in a plant cell, does not reasonably provide enablement for a method of making a localized mutation in any target gene in a plant cell. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 March 2002. Applicant's arguments filed 7 June 2002 have been fully considered but they are not persuasive.

Applicant argues that the present claims are directed to methods of making localized mutations-mutations to genes that are known in the art and that have been sequenced at least in the region where the mutation is desired and that all of the present claims require the recombinagenic oligonucleobase to contain regions that are both homologous and heterologous to the native gene being mutated (see last paragraph on page 3 of the Remarks). Applicant argues that the Walker Declaration

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(filed 29 December 1999) is evidence that the present claims are enabled (see page 4, 2nd paragraph of the Remarks). The Examiner responds that the instant rejection is not an enablement rejection, but rather a scope of enablement rejection. The instant claims are broadly drawn to a method of making a localized mutation causing a desired trait in a target gene in a plant cell, wherein any target gene is mutated. Applicant has provided limited guidance for producing a desired trait, that being mutating *in situ* a plant ALS gene. The Examiner notes the GFP (green fluorescent protein) is not a protein encoded by a plant gene. In addition, the art teaches that at the time of Applicant's invention the art was unpredictable as outlined in the previous Office action and required empiric evidence to successfully practice the claimed method. Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make a localized mutation causing a desired trait in any target gene in any plant cell as broadly claimed.

Claim Rejections - 35 USC § 102

5. Claims 1 and 16 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Svab *et al* 1990 (Proc. Natl. Acad. Sci. USA 87:8526-8530). This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 March 2002. Applicant's arguments filed 7 June 2002 have been fully considered but they are not persuasive.

Applicant argues that Svab does not disclose a method of making a localized mutation in a target gene but that Svab discloses the TRANSFORMATION of a plant chloroplast with a mutated gene, and hence does not anticipate the instant claims (see

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page 4, last paragraph of the Remarks). This is not found to be persuasive because the instant claims encompass homologous recombination using a "recombinagenic oligonucleobase" comprising at least 1 nucleobase heterologous to the target gene. Applicant's attention is directed to page 8528, left column, second paragraph of Svab which states that the "recombinagenic oligonucleobase" of Svab was incorporated into the plant chloroplast genome by a homologous recombination event, hence all of the claim limitations have been previously disclosed by Svab.

Claim Rejections - 35 USC § 103

6. Claims 1-4 and 8-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (U.S. Patent 5,731,181, filed 17 June 1996) in view of Dunder *et al* (in Gene Transfer To Plants 1995, Potrykus and Spangenberg, Eds., Springer Verlag publisher, Chapter 15, pages 127-138) and in view of Applicant's admission. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 March 2002. Applicant's arguments filed 7 June 2002 have been fully considered but they are not persuasive.

Applicant argues that Kmiec taught the use of recombinagenic oligonucleobases to produce localized mutations but not with the gene gun or biolistic methods (see page 5 of the Remarks). This is not found to be persuasive because Kmiec teaches that cells can be transfected with the CMV (syn. MDON) by any technique now known or to be developed for transfecting cells with DNA. In the instant case, biolistic introduction of DNA in to plant cells was well known in the art at the time of Applicant's invention.

Applicant argues that Dunder teaches transformation of plant cells (see page 5 of the Remarks). This argument is misplaced because the teachings of Dunder have been cited as evidence that introduction of DNA into a plant cell using a biolistic method was known in the art at the time of Applicant's invention. It's the combination of the teachings of Dunder and the teachings of Kmiec that render the claimed invention obvious.

Applicant argues that the Kmiec recombinagenic nucleobase technology was known however the short regions of secondary structure are critical to its function and that biolistic transformation technology involved large pieces of DNA that contained whole genes and regulatory sequences. In addition, Applicant argues that the biolistic transformation technology employed harsh chemical and physical conditions in delivering the DNA into the plant cell, conditions whose effects on recombinagenic oligonucleobases was unknown at the time of the present invention was made (see page 5 of the Remarks). This argument is not found persuasive because the instant claims are not directed to a method of introducing a recombinagenic oligonucleobase comprising a mixed duplex oligonucleotide, but to a method of making a localized mutation in a target gene in a plant cell. It is noted that claims 1 and 16 do not recite any critical limitations for introducing a MDON into a plant cell that leads to a teaching of unexpected results over that taught in the prior art at the time of Applicant's invention. In addition, the specific limitations cited in claim 8 appear to be conditions commonly used in the art to practice the method of introducing DNA into a plant cell using a biolistics. Hence, the instant claims remain obvious for the reasons given in the

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previous Office action and do not lead to the teachings of unexpected results. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
21 August 2002